



Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

01-BLT-23

March 20, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Johnny C. Chan, Co-owner
Happy Valley Food, Inc.
1240 W Street, N.E.
Washington, D.C. 20018

Mr. Tony W. Chan, Co-owner
Happy Valley Food, Inc.
1240 W Street, N.E.
Washington, D.C. 20018

Dear Mr. Chan:

The Food and Drug Administration (FDA) conducted an inspection of your manufacturing/warehousing facility located at 1240 W Street, N.E., Washington, D.C., on February 22 and 27, 2001. The inspection revealed numerous deviations from the Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (CFR), Part 110. At the conclusion of the inspection, you were issued a Form "FDA-483" Inpectional Observations (copy enclosed) which described the insanitary conditions in your firm during the inspection. These conditions cause the products manufactured and stored in your facility to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (the Act). The conditions observed included:

- A live rodent in the warehouse (Observation #1).
- Rodent gnawed products (carrots, chicken wings, egg rolls, and beef tips) located in the warehouse and the freezer (Observations #3A/B).
- Rodent excreta droppings on the floors throughout the warehouse (Observation #4A/H).
- Eight live birds flying in the warehouse (Observation #2).
- Bird droppings (on shelves and the floors) in the warehouse and cooler (Observation #6A/E).
- Dead flies in the cooler (Observation #5).
- Food debris and dents in a colander used to hold shredded cabbage (Observation #7).
- An uncovered colander holding shredded cabbage stored in the cooler beneath a box. Water was dripping from the box onto the cabbage (Observation #8).
- Trash and debris along warehouse walls and product storage directly against walls in the warehouse (Observations #9 and #11).
- Food debris on the floors in all of the coolers and freezer (Observation #10).
- Holes in the cinderblock walls that penetrate through to the hollow part of the blocks (Observation #12).
- Standing water in several areas of the warehouse (Observation #13A/C).
- Loading doors remained open during the entire inspection (Observation #14).
- Bird entryways into the firm (Observation #15).

Mr. Johnny C. Chan and Mr. Tony W. Chan
Page 2
March 20, 2001

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Rosalie Bucey, Compliance Officer. Ms. Bucey can be reached at 410/962-3591, extension 143.

Sincerely,



Lee Bowers
Director, Baltimore District

Enclosure